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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/484,886	01/18/2000	Gale E. Smith	674506-2035.2	1236

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EXAMINER
SRIVASTAVA, KAILASH C

ART UNIT	PAPER NUMBER
1651	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/484,886	SMITH ET AL.	
	Examiner	Art Unit	
	Dr. Kailash C. Srivastava	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *12/17/2002 as Paper Number 10* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *43-116* is/are pending in the application.

4a) Of the above claim(s) *43-89 and 91-95* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *90 and 96-116* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a)☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *6 and 8* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicant's response and amendment filed December 17, 2002 as Paper Number 10 to election requirement in Office Action mailed October 17, 2002 as paper Number 9 is acknowledged and entered.

2. Claims 43-116 are presented for examination.

Restriction/Election

3. Applicants' election with traverse of Group IV, Claim 90 filed December 17, 2002 as Paper Number 10 to election requirement in Office Action mailed October 17, 2002 as paper Number 9 is acknowledged and entered. Applicants' election of erythropoietin as the expressed product in the response filed December 17, 2002 as Paper Number 10 is also acknowledged and entered.

Applicants' traversal is on the ground (s) that inventions encompassed in Groups I-IV are inter-related and therefore, a search for claims encompassed in groups I-IV together would not place an additional burden on the examiner. Applicants further state that the Office Action mailed October 17, 2002 as paper Number 9 does not adequately demonstrate 'that the examination of more than one Group would present an undue burden on the Examiner". Referring to the Examination of Claims 1-95 under PCT and according to Office Action mailed March 18, 2002 as Paper Number 7, applicants further argue that "the prosecution to date and the International Prosecution of the corresponding PCT application demonstrate that there is no undue or serious burden in searching and examining all of the Groups I to IV in this application, and mandate against restriction as set forth in the instant Office Action".

Applicants' arguments discussed supra have been fully considered but are not persuasive because of the reasons of record under item 7 on Page 4 paragraphs 3-4, in Office Action mailed October 17, 2002 as paper Number 9. As pointed out in the citation referred to supra, there indeed are 4 different inventions because of their separate status in the art, different classification (Class and subclass) and their recognized subject matter. Furthermore, the search for each of the distinct inventions of Groups I-IV or even III-IV is not co-extensive particularly with regard to the literature search because inventions in Groups I-III pertain to a method, while invention in

Group IV pertains to a composition (i.e., an expressed product, namely erythropoietin). Further, a reference that would anticipate the invention of one group would not necessarily anticipate or even make obvious another group. Finally, the condition for patentability is different in each case. Thus, it will be an undue burden to examine all of the inventive Groups in one application. Further, the actions of another Office (i.e., PCT) or even another examiner (i.e., the examiner for Office Action mailed March 18, 2002 as Paper Number 7) are not binding. Therefore, the restriction requirement is still deemed proper and is made FINAL.

4. Claims 90 and 96-116 are examined on merits.

Priority

5. Applicant's claim for domestic priority under 35 U.S.C. §§119(e) and 120 is acknowledged.

Specification

The amendment filed 12/17/2002 as paper Number 10 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure as filed is as follows: Example 9.

Applicant is required to cancel the new matter in the reply to this Office Action.

Claim Rejections - 35 U.S.C. § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> ***The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter, which the applicant regards as his invention.***

7. Claims 90 is rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

- Claim 90 is dependent on a non-elected invention. Appropriate correction is requested.
- Claim 90 is dependent on a non-elected species. Appropriate correction is requested.

Claim Rejections – 35 U.S.C. § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. § 102 that form the basis for the rejections under this section made in this Office action:

> ***A person shall be entitled to a patent unless –***
>
> ***(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.***

9. Claims 90, 96-97 and 99-116 are rejected under 35 U.S.C. §102(b) as anticipated by Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) with evidence provided by Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581).

Claims recite a glycosylated, >95% pure, recombinant erythropoietin produced by a baculovirus expression system in a cultured insect cell, wherein said erythropoietin has an activity between 200,000 U/mg to 500,000 U/mg and said erythropoietin stimulates erythropoiesis. Thus, Claims recite a glycoprotein having the properties that are discussed supra.

Quelle et al., disclose a glycosylated, >99% pure, recombinant human erythropoietin produced by a baculovirus expression system, said expression system cultured in an insect cell, wherein said erythropoietin has an activity of 200,000 U/mg protein (Page 652, Column 1, Lines 6-25 and Column 2, Lines 6-13). Please note that erythropoiesis is an inherent activity of erythropoietin (See Dorland's Illustrated Medical Dictionary, Page 581, Column 1, Lines 38-41).

Therefore, the reference deems to anticipate the cited claim.

Please note that Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581) is merely to support that erythropoiesis is an inherent activity of erythropoietin and is not cited as a prior art reference.

Claim Rejections - 35 U.S.C. § 103

10. The following is a quotation of 35 U.S.C. §103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> ***(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.***

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. § 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. § 103(c) and potential 35 U.S.C. § 102(f) or (g) prior art under 35 U.S.C.§ 103(a).

12. Claim 98 is rejected under 35 U.S.C. § 103 (a) as obvious over Quelle et al. (Blood. 1989. Volume 74, Pgs. 652-657) with evidence provided by Dorland's Illustrated Medical Dictionary (W.B. Saunders Co., Philadelphia, 1988, Page 581.

Claims recite a glycosylated, >95% pure, recombinant erythropoietin produced by a baculovirus expression system in a cultured insect cell, wherein said erythropoietin has an activity 500,000 U/mg and said erythropoietin stimulates erythropoiesis.

Teachings from Quelle et al. with evidence provided by Dorland's Illustrated Medical Dictionary have already been discussed *supra*. Quelle et al. lacks EPO purified to 500,000 U/mg.

The advantages of further purifying a partially-purified protein/hormone, for which receptors have been recognized and for which a use is known, provide sufficient reason to find the purified protein/hormone to have been obvious to one of ordinary skill at the time of the invention. Some of the advantages of the purification being, that purified protein/hormone: are more storage-stable; generally exhibit an increased specific activity; are amenable to amino acid sequencing which can lead to recombinant means of protein/hormone production with its accompanying savings in costs; and, allow for ready separation of reaction products as compared to separations which must account for impurities. These advantages are well known to the artisan of ordinary skill. Such knowledge may provide the suggestion to modify the explicit teachings of the relied upon reference or to combine references. See Ashland Oil, Inc. v. Delta Resins & Refractories, Inc., 776 F.2d 281, 297 n.24, 227 USPQ 657, 667 n.24 (Fed. Cir. 1985). The position taken is that well known purification techniques would be employed with a reasonable expectation of success in providing a purified product possessing the claimed properties. Thus, an "obvious to try" standard is not being applied herein. See In re O'Farrell, 853 F.2d 894, 903-904, 7 USPQ2d 1673, 1681 (Fed.Cir. 1988).

One having ordinary skill in the art would have been motivated to modify the teachings from Quelle et al. according to the teachings generally known to one of ordinary skill at the time of the invention, as discussed in preceding paragraph.

The instant invention is a product-by-process. Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps. According to MPEP§2113, "even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior art product was made by a different process." In re Thorpe, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (Citations omitted). In instant invention, the claimed erythropoietin product is clearly documented in the cited prior art.

Thus, it would have been prima facie obvious to one of ordinary skill in the art at the time the invention was made to modify teachings from Quelle et al. to further purify erythropoietin (i.e., EPO).

From the teachings of the reference cited supra, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was prima facie obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

Conclusion

13. No Claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Kailash C. Srivastava whose telephone number is (703) 605-1196. The examiner can normally be reached on Monday-Thursday from 7:30 A.M. to 6:00 P. M. (Eastern Standard Time or Eastern Daylight Saving Time).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743 Monday through Thursday.

The fax phone number for the organization where this application or proceeding is assigned is (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

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Art Unit 1651
(703) 605-1196

March 24, 2003

Jon P. Weber, Ph.D.
Primary Examiner